

BRIEF ON APPEAL	Application #	08/981,665
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	First Inventor	CIPKOWSKI
	Art Unit	1641
	Examiner	Grun, James Leslie
	Docket #	P08948US01/BAS

Mail Stop Appeal Brief - Patents
 Commissioner for Patents
 P.O. Box 1450
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APPEAL FROM THE FINAL REJECTION
MAILED DECEMBER 28, 2009

<u>TABLE OF CONTENTS</u>	Page
1. REAL PARTY IN INTEREST	1
2. RELATED APPEALS AND INTERFERENCES	2
3. STATUS OF CLAIMS	3
4. STATUS OF AMENDMENTS	4
5. SUMMARY OF CLAIMED SUBJECT MATTER	5
6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL	6
7. ARGUMENT	7
8. CLAIMS APPENDIX	17
9. EVIDENCE APPENDIX	20
10. RELATED PROCEEDINGS APPENDIX	21

1. REAL PARTY IN INTEREST

The real party in interest is the recorded assignee, American Bio Medica Corporation.

2. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

3. STATUS OF CLAIMS

Claims 16 and 18-19 are currently pending and on appeal.

No claims are objected to as being dependent on a rejected base claim but allowable if rewritten in independent form.

Claims 1-15 and 17 have been canceled.

The rejections of independent claim 16 and dependent claims 18-19 are being appealed.¹

¹ Although not addressed herein, there is a minor objection to Claim 16 under 35 U.S.C. § 112 in that the word "the" before "fluid sample" should be replaced by the word "a". Applicants would consent to this change as an Examiner's amendment if so required.

4. STATUS OF AMENDMENTS

No amendment was filed after the Final Rejection dated December 28, 2009.

5. SUMMARY OF CLAIMED SUBJECT MATTER

The subject matter of the claims upon appeal relates to a test card for testing a liquid test specimen for the presence or absence of a drug of abuse as set forth in independent Claim 16 of the pending application. In short, Applicants' claimed invention as shown, e.g., in Fig. 1, relates to a thin flat test card for assaying drugs of abuse which contains a plurality of conventional test strips which are housed inside the test card. These test strips are placed flat inside the test card so that the sample contacting portion of the test strip is directly below an opening of the test card, e.g., as shown in the specification at page 12, lines 7-9 wherein it is disclosed that there are "sample openings 51 through which the liquid test specimen is able to contact the absorbent or sample portions of the test strips." As is specifically disclosed at page 11, lines 18-20 of Applicants' specification, the test card has an opening for the test strip to be contacted by a fluid sample and a test portion wherein the result of the test (positive or negative) will be observed. In this passage, the specification discloses that in the modified test card of Fig. 9, "the test strips are covered but the pertinent test and sample portions of the test strips are exposed through openings." This pattern is also shown in the modified version disclosed as Fig. 11.

As indicated herein, the claimed subject matter is clearly and unambiguously disclosed in Applicants' specification.

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

In the first ground of rejection to be reviewed upon Appeal, the Examiner has rejected Claims 16, 18 and 19 under 35 U.S.C. §112, first paragraph, as containing subject matter which was allegedly not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the present inventors had possession of the claimed invention.² However, as shown below, such a rejection is improper since the specification clearly and unambiguously discloses the claimed features.

In the second ground of rejection to be reviewed upon Appeal, the Examiner has rejected Claims 16, 18 and 19 under 35 U.S.C. §103 (a) as allegedly being unpatentable over May et al. PCT application WO 88/08534 in view of Sun et al. (US 5,238,652) and further in view of Boger et al. US 4,518,565. However, as shown below, such a rejection is improper in light of the fact that none of these references discloses the claimed invention, nor can the references be combined to come up with the claimed invention, and moreover the references actually teach away from the pending claims.

² The Examiner also rejected the specification, but not any claims, under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure. See Final Rejection at page 2, line 8. The Examiner provides no basis for the alleged enablement rejection, does not refer to the *Wands* factors, and makes no further arguments as to why the claims are not enabled by the specification. Moreover, the Examiner actually concedes that one skilled in the art could realize from reading the disclosure that absorbent or sample receiving portions on the exposed or front surface of the test strips are usable in the invention. See Final Rejection at page 4, lines 3-6. Applicants thus submit that the claims are fully enabled, and combined with the fact that there are no claims rejected on the basis of enablement, no further argument is necessary on this point.

7. ARGUMENT

A. THE EXAMINER'S REJECTION UNDER 35 U.S.C. § 112 IS IMPROPER AND
SHOULD BE REVERSED

In the Final Rejection, the Examiner rejected Claims 16, 18 and 19 under 35 U.S.C. §112, first paragraph, for failure to comply with the written description requirement. The Examiner's ostensible basis for this rejection was that the specification does not provide support for

"a sample **contacting** portion **on the exposed surface** (i.e., front) **of the test strip** so that liquid sample flows through the sample opening in the thin flat member strip holder and contacts the **exposed surface** (i.e., front) of the sample portion directly beneath (i.e., registering with) the opening."

See Final Rejection, page 2 (emphasis by Examiner). Such a position is completely unfounded since the specification unambiguously shows these features.

In short, Applicants' claimed invention as shown, e.g., in Fig. 1, relates to a thin flat test card for assaying drugs of abuse which contains a plurality of conventional test strips which are housed inside the test card. These test strips are placed flat inside the test card so that the sample contacting portion of the test strip is directly below an opening of the test card. This is clearly and unambiguously shown in Applicants' specification, e.g., page 12, lines 7-9 wherein it is disclosed that there are "sample openings 51 through which the liquid test specimen is able to contact the absorbent or sample portions of the test strips." The fact that the test card has an opening at the test portion and the sample portion with the underlying regions of the test strip exposed through said openings is specifically disclosed at page 11, lines 18-20 wherein the

specification states that in the modified test card of Fig. 9, "the test strips are covered but the pertinent test and sample portions of the test strips are exposed through openings." This pattern is also shown in the modified version disclosed as Fig. 11.

Accordingly, the specification clearly and unambiguously discloses the claimed subject matter and moreover, the Examiner's only position appears to be based on his own confusion regarding what Applicant meant by "conventional test strip." A conventional test strip, as shown in the specification and drawing figures, is a long thin flat strip that fits into the test card such that the sample contacting portion of the test strip is directly below a corresponding opening in the test card. Compare Figs. 11 (front of the test card showing top ply 47 which fits over the test strips) and 12 (showing of test strips in ply 45 just below the front of test card). Specifically, the test strip 53 as shown in Fig. 12 (see specification at page 12, lines 18-20) is directly below the corresponding sample openings 51 as shown in Fig. 11 which is described as the openings through which the liquid test specimen is able to contact the "absorbent" or "sample" portions of the test strips. This embodiment is thus exactly as described in the claims, and thus the drawing figures and specification disclose the invention exactly as claimed.

Finally, the Examiner himself concedes that the claimed subject matter could be understood by one skilled in the art as having been one of the embodiments disclosed in Applicants' specification. See Final Rejection page 4, lines 3-6. The fact that the Examiner has at most said that the wording of the claims could be subject to a different interpretation is irrelevant to the issue of the written description requirement. See *In re Wright*, 9 USPQ2d 1649 (Fed. Cir. 1989) where under similar circumstances, the Federal Circuit reversed a written description rejection and held that the Board's

position that the disputed claim words were open to different interpretation "went to the *scope* of the phrase rather than the support for it and was deemed an irrelevant inquiry. These are common, garden variety words known to every English-speaking person." 9 U.S.P.Q.2d at 1651. Similarly, in the present case, the plain language of the claims is supported by the specification, including both the language and the drawings, and one skilled in the art would readily understand that the Applicants were in possession of the claimed subject matter at the time of the invention.

Accordingly, the Examiner's rejection under the written description requirement of Section 112 is entirely improper and should be reversed.³

³ As indicated above, there is another non-substantive objection to Claim 16 in that the word "the" before "fluid sample" should be replaced by the word "a", but Applicants would consent to this change as an Examiner's amendment if so required.

B. THE EXAMINER'S REJECTION UNDER 35 U.S.C. § 103(A) IS IMPROPER
AND SHOULD BE REVERSED

In the Final Rejection, the Examiner has rejected Claims 16, 18 and 19 under 35 U.S.C. §103 (a) as allegedly being unpatentable over May et al. PCT application WO 88/08534 in view of Sun et al. (US 5,238,652) and further in view of Boger et al. US 4,518,565. However, as shown below, such a rejection is improper in light of the fact that none of these references discloses the claimed invention, nor can they be combined in any manner to come up with the claimed invention. Moreover, as detailed below, the references actually teach away from the pending claims.

As indicated above with regard to the written description rejection, the Examiner appears to be confused with regard to the subject matter of the claimed invention, which is a test card, as opposed to the Examiner's repeated focus on the test strips therein which are conventional elements and not reflective of the improvements provided by the present invention. In the Final Rejection, the Examiner's main points for maintaining the rejection was that (1) Applicant admitted that test strips were commercially available (see Final Rejection, bottom of Page 7, "Applicant also clearly admits that the test strips for performance were commercially available."); and (2) that Applicants' arguments have "attacked the references individually" and thus cannot show unobviousness when the rejections are based on combinations (see start of second full paragraph on Page 7).

However, in stark contrast to the Examiner's positions, Applicant's claims are **not** directed to a test strip but a **test card**. Moreover, as shown below, Applicants have not "attacked the references individually" but instead have shown conclusively that those references, either singly or in combination, nowhere disclose or make obvious in any way a test card containing features in accordance with the claimed invention, and to the contrary **teach away** from the claims.

With regard to the Examiner's reference to the fact that "Applicant clearly admits that the test strips for performance of the immunoassay were commercially available", this should not have come as a surprise to the Examiner since Applicant's disclosure plainly states that these test strips are conventional (e.g., see bottom of page 8 to top of page 9 where Applicant states "Test strips 26-30 may be of the type as made by Bionike of South San Francisco, California, Pharmatech of San Diego, California and Arista Biological of Bethlehem, Pennsylvania.") Once again, by focusing on the conventional test strips, the Examiner has missed the points of distinction over the prior art which have nothing to do with the strips and everything to do with the specific configuration of the test card as described in Applicant's claims. As shown below, indeed neither the cited May reference, nor the other citations Sun and Boger, disclose or suggest the claimed invention either singly or in combination.

In fact, the Examiner's repeated allegation that Applicant is "attacking the references individually" when in fact the rejections were based on a combination of references (see, e.g., page 7, start of second paragraph) also reflects that the Examiner has not made a proper rejection. While this general principle may be appropriate wherein the Examiner has located elements of the claimed invention in two different

references and then argues that the combination of the two references makes the invention obvious, it is **not** appropriate in the case where, as here, the Examiner has not shown that the essential elements of the claimed invention are located in **any** reference, much less in a combination of references. For example, an obviousness rejection to a claimed combination of A and B may be appropriate when the Examiner cites reference 1 showing "A" and reference 2 showing "B", and then provides a reason why one skilled in the art would combine the two.

However, **this is not the case with the Examiner's current rejections.** To the contrary, the Examiner is citing the May reference (WO 88/08534), the Sun reference (US patent 5,238,652) and the Boger reference (US 4,518,565), **none of which disclose the specific test card of the present invention**, namely one wherein the test card houses one or more immunoassay strips wherein the liquid specimen passes through the opening directly above the sample contacting portion on the front of the test strip and then proceeds via capillary action along the strip to the test portion wherein an analyte in the specimen may be visually determined through another opening in the test card.

To the contrary, the main reference cited by the Examiner, the May reference **teaches away** from the present claims because the device disclosed therein **covers up** in all cases the front surface of the test strip and **prevents** the sample from contacting the test strip on the front surface of the strip. In particular, as best shown in Figs. 11 and 12 in May, this reference discloses a device wherein the fluid sample is directed through opening 601 which is not a sample contacting portion of a test strip (element 606) and is in fact not even directly over the test strip 606 itself. Instead, the fluid

sample is contacted only through the end of the test strip 606 which is blocked from receiving a fluid sample on the front end of the test strip. May thus discloses a device which is fundamentally different than the claimed invention because there is no sample contacting portion on the front surface of the test strip and instead there is a sample opening which only exposes the end of a porous member through which the specimen must pass before it can even contact the absorbent part of the test strip.

The May reference thus directs one skilled in the art **away** from the present invention because the fluid is contacted at the lower edge and not the front of a test strip as in the claims, and the blocking of the front surface of the test strip would discourage one skilled in the art from carrying out the invention as claimed in the present application. The fact that the cited May reference would encourage one skilled in the art to take an entirely different path than the one embodied in the claimed invention shows that this reference **teaches away** from the present invention and thus further shows that the present claims are not made obvious by the cited references. See *In re Gurley*, 31 U.S.P.Q.2d 1130, 1131 (Fed. Cir. 1994) ("A reference may be said to teach away when a person of ordinary skill, upon reading the reference, . . . would be led in a direction divergent from the path that was taken by the applicant.")

Moreover, there is nothing in the cited Sun or Boger references which could be added to overcome the deficiencies in the May references. In particular, the Sun reference also does not disclose a test card with a sample contacting portion on the front surface of the test strip, and even further, the Examiner has previously conceded that the Sun reference does not have openings exposing the test portions of the strips. See, e.g., the prior Decision on Appeal in this application (March 31, 2003), at page 4.

Further, the Examiner merely cited the Boger et al. reference for the fact that it shows "ridges or other means which facilitate the preferred parallel alignment of the strips". However, the Examiner concedes that Boger does not disclose any of the crucial elements as recited above, namely a test card having an opening over the exposed sample contacting portion of the test strip. To the contrary, Boger is totally unrelated to the present invention and does not disclose or suggest **any** immunoassay test strip whatsoever. Instead, Boger is directed to a holder for positioning and retaining a number of individual reagent pads for sampling which does not involve any lateral flow test strips nor permit for a reading of any samples while in the holder. Boger's device involves applying the test sample to a single non-flowing spot, and this is completely different than the later flow immunoassay conducted in accordance with the test card of the present application. The Examiner's description of the Boger et al. reference once again concedes that this reference also does not disclose or suggest Applicant's claimed features and thus cannot be added to the May or Sun reference to make the present claims obvious.

The Examiner thus cannot make a proper rejection based on a combination of reference when **there is nothing to combine** from the May, Sun or Boger references which would together disclose the elements of the present claims directed to a test card, much less make those features obvious. To the contrary, as set forth above, the May reference teaches an immunoassay device that operates in a manner that is **completely opposite** to the manner of operation of Applicant's test card, namely one in which the front surface of the immunoassay test strip is **blocked** from receiving a sample and the sample can **only** contact the test strip from a lower edge. Instead,

Applicant's invention specifically **avoids** and **overcomes** the problems associated with the prior art immunoassay test devices such as shown in May by having a sample contacting portion in the test card whereby the sample can directly contact the front surface portion of the test strip. Moreover, nothing in the cited Sun or Boger references overcomes the deficiencies in the May reference. Since there is nothing in the cited references which discloses or remotely suggests Applicant's test card, these references do not, either singly or in combination, disclose or suggest Applicant's claimed invention, and indeed since the device of May acts in a manner to **prevent** an embodiment of the type set forth in Applicant's claims, the prior art actually **teaches away** from the present invention and further supports the nonobviousness of the claims.

Applicants thus submit that the Examiner's rejection for obviousness under 35 U.S.C. §103(a) is respectfully traversed and should be reversed.

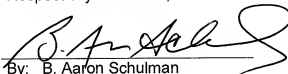
C. CONCLUSION

For the foregoing reasons, it is submitted that independent claim 16 is adequately described in the specification, and is unobvious over the references cited by the Examiner which **teach away** from the claimed subject matter.

Therefore, the examiner should be **reversed** with respect to the rejections of the this independent claim; as well as all remaining claims which are dependent from this independent claim.

Respectfully submitted,

Date: September 7, 2010


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8. CLAIMS APPENDIX

The following claims are on Appeal:

16. A drug of abuse immunoassay test card for testing a liquid test specimen in a container having an open top and comprising a thin flat member having a rectangular outline and having front and rear surfaces, said thin flat member having a longitudinal dimension extending between top and bottom ends defining a length and having a width less than said length, and being shaped to be insertable longitudinally into a container to contact a liquid test specimen therein, one or more immunoassay test strips each having thereon immunoassay means to visually indicate presence or absence of a selected drug of abuse disposed longitudinally side-by-side in parallel within said thin flat member and enclosed between said front and rear surfaces, each said one or more test strips having a bottom end defining a sample contacting portion and further having a test portion spaced longitudinally therefrom wherein, in use, the liquid test specimen moves by capillary action from the sample contacting portion to the test portion at which the presence or absence of the selected drug of abuse in the fluid sample is visually indicated, the bottom end of each said one or more test strips being disposed at the bottom end of said thin flat member but spaced from the bottom end of said thin flat member, the top end of each said one or more test strips being spaced from the top end of said thin flat member, said front surface of said thin flat member having a plurality of openings therein to register with and expose each of the sample contacting and test portions on the exposed surface of each of said one or more test strips exposed by said openings, including a sample contacting opening over said

sample contacting portion of the test strip and a test opening over said test portion of said test strip, said openings located so that the liquid test specimen initially travels through said sample contacting opening and contacts the exposed surface of the sample contacting portions of each of said one or more test strips exposed beneath said sample contacting openings and then moves by capillary action from the sample contacting portion of said one or more test strips to the test portion of said one or more test strips,

further comprising means within said thin flat member between said front and rear surfaces for defining one or more longitudinally extending slots to longitudinally dispose said one or more test strips, each said one or more slots having both ends closed and spaced from the respective top and bottom ends of said thin flat member, and said one or more immunoassay test strips each seated within a respective slot.

18. The drug of abuse immunoassay test card as claimed in claim 16 wherein said thin flat member comprises a central ply having a first thickness sandwiched between a top ply defining said front surface and a bottom ply defining said rear surface, there being a plurality of side-by-side parallel longitudinally extending slots in said central ply to longitudinally dispose said test strips, said slots having both ends thereof closed and spaced from the respective top and bottom ends of said thin flat member, and said immunoassay test strips each seated within a respective slot.

19. The drug of abuse immunoassay test card as claimed in claim 16 wherein said thin flat member has a thickness substantially equal to the thickness of said test strips.

9. EVIDENCE APPENDIX

None

10. RELATED PROCEEDINGS APPENDIX

None